K062504

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510(k) Summary

SEP - 5 2006

Date: June 10, 2006

1. Company making the submission:

	Submitter
Name	Alphadent Co., Ltd.
Address	371-37, Gasan-Dong, Geumcheon-Gu, Seoul, Republic of Korea 153-803
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Contact	Mr. Noh Hak
Internet	http://www.alphadent.co.kr

2. Device :
   Proprietary Name – CeraMax
   Common Name – Dental Ceramic
   Classification Name – Porcelain powder for clinical use

3. Predicate Device: DUCERAM PLUS CERAMIC SYSTEM, Porcelain powders
   Dentsply International Company. K040420.

4. Description :
   CeraMax is a dental material product composed of Feldspar, Quartz (SiO_2), Al_2O_3, K_2CO_3, Na_2CO_3, SnO_2, ZrO_2, CeO_2 Li_2CO_3, $BaCO_3$, $CaCO_3$, H_3BO_3 and color pigments including Fluorolumin. It consists of Opaque (including Powder opaque, Paste opaque and Opaque modifier), Dentine (including Dentine modifier and Opacious Dentine), Enamel, Translucent, Cervical, Glaze and Stain. They are used by dental technicians for the preparation of crowns and bridges. It is used in prosthetic dentistry by heating the powder mixture to a high temperature in a furnace to produce a hard prosthesis with a glass-like finish.

5. Indication for use :
   CeraMax is indicated for veneering of metal framework and copings for the preparation of crowns and bridges.

6. Review :
   CeraMax has the similar technological characteristics to the predicate device; components, indication for use, chemical and performance properties.

   Components Similarities
   Both products are supplied as a powder for mixing together with a liquid to form a paste or as a paste to apply for thinner and easier usage. Both products are supplied with different layers i.e.: Opaque, Dentine and Enamel etc., that have different name. However they functionally are same

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in order to replicate different color layers in a natural tooth. These layers are built up and fired in a furnace in the similar order and at similar temperature.

Indication for Use Similarities
Both products have the similar indication for use.

Chemical Similarities
Both products are made up of porcelain powders and are used in a dental ceramic veneering system of metal framework and copings to form an enamel porcelain layer. They are supplied with different layers i.e.: Opaque, Dentine, Enamel etc. in order to replicate different color layers in a natural tooth. They fall within the same class and have a product code.

Performance Properties Similarities
Both products have essentially the similar firing characteristics including starting temperature, drying time, final temperature and requirement of vacuum. They also manufactured, conforming ISO 9693, ISO 6872. These standards specify performance criteria such as physical properties, glass transition temperature, flexural strength and chemical solubility so that the results of performance meet the requirements of the international standard in accordance with ISO 9693 and ISO 6872.

Biocompatibility of CeraMax is similar to the legally marketed devices and has not changed to occur adverse effects of biocompatibility. Therefore, it was determined that no additional biocompatibility testing was necessary.

Therefore, we believe that CeraMax is substantially equivalent to predicated device according to the above information in terms of component, indication for use, chemical and performance priorities.

7. Conclusions :

Based on the information provided in this premarket notification Alphadent Co., Ltd. concludes that CeraMax is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

Alphadent Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 North West Lake Road
Camas, Washington 98607-9526

Re: K062504
Trade/Device Name: CeraMax
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 16, 2006
Received: August 28, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K062504

Device Name: CeraMax

Indications for Use:

CeraMax is indicated for veneering of metal framework and copings for the preparation of crowns and bridges.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(21CFR801 Subpart D) (21CFR801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(Division Sign-Off) Number: K062504